

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)
)
Plaintiff,)
v.)
)
BOSTON SCIENTIFIC CORPORATION and)
SCIMED LIFE SYSTEMS, INC.,)
)
Defendants.)

C.A. No. 98-197-SLR

**CORDIS' PROPOSED FINDINGS OF FACT AND
CONCLUSIONS OF LAW ON INEQUITABLE CONDUCT**

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Plaintiff Cordis respectfully submits these proposed findings of fact and conclusions of law on inequitable conduct as requested by this Court on September 12, 2006 following the remand of this case from the Federal Circuit.

Prior Proceedings

In this action, Cordis alleges that BSC's NIR stent infringes U.S. Patent No. 5,879,370, which issued in March 1999 to Dr. Robert Fischell and his sons Dr. David Fischell and Dr. Tim Fischell. The application for the '370 patent was filed in 1997 as a continuation of the patent that issued as U.S. Patent No. 5,643,312.

After a trial in the Fall of 2000, the jury returned a verdict that BSC's NIR stent literally infringes claim 25 of the '370 patent, but avoids infringement under the reverse doctrine of equivalents. The jury rejected BSC's validity defense for that claim, based on the written description requirement.

Claim 25 of the '370 patent depends from claim 22, which is directed at a pre-deployment balloon-expandable stent adapted for percutaneous delivery to the curved coronary arteries, with the stent having a multiplicity of closed perimeter cells, and with each cell having one or more undulating sections whose end points are on a line that is generally parallel to the stent's longitudinal axis. Claim 25 adds a requirement that the undulating sections comprise a "U" shaped curve. As explained in the specification (at col. 3, lines 47-50), a stent with undulating longitudinals will "bend more easily during insertion into a vessel."

In February 2001, the Court held a non-jury hearing on inequitable conduct.

On March 28, 2002, this Court ruled on inequitable conduct and on the parties' post-trial motions for JMOL. As to infringement, this Court granted BSC's motion for JMOL setting aside the verdict of literal infringement of the '370 patent, and denied as moot Cordis' motion for JMOL on the reverse doctrine of equivalents. As to validity, this Court denied BSC's

motion for JMOL on its written description defense. As to inequitable conduct, this Court held that the '370 patent is unenforceable due to nondisclosure of Hillstead's U.S. Patent 4,856,516 ("Hillstead") during prosecution of the related '312 patent. D.I. 255.

This case was then stayed pending appeal and retrials in the related case captioned Cordis Corp. v. Medtronic Vascular, Inc., C.A. No. 97-550-SLR.

Following the entry of judgment on May 2, 2005, Cordis appealed from the grant of JMOL of noninfringement and from the ruling that the '370 patent is unenforceable. BSC cross-appealed from the denial of its motion for JMOL on the written description issue.

In a decision dated June 29, 2006, the Federal Circuit affirmed this Court's denial of JMOL on the written description issue and remanded the case to this Court for additional findings of fact on inequitable conduct. Cordis Corp. v. Boston Scientific Corp., 2006 WL 1876839 (Fed. Cir. June 29, 2006) (unpublished). The Federal Circuit did not reach the issues concerning literal infringement and the reverse doctrine of equivalents.

As to inequitable conduct, the Federal Circuit remanded for additional findings of fact on two issues: (1) whether there was an intent to deceive the PTO during prosecution of the '312 patent; (2) whether there is an "immediate and necessary relation" between the '370 patent and the alleged inequitable conduct in the '312 patent.

In a teleconference on September 12, 2006, this Court asked the parties to submit proposed findings on the issues identified by the Federal Circuit. Cordis respectfully submits its proposed findings on these issues.

Preliminary Statement

BSC does not, and cannot, suggest that there was any inequitable conduct during prosecution of the application that issued as the '370 patent. Instead, BSC contends that the non-

disclosure of the Hillstead '516 patent during prosecution of the '312 patent was inequitable conduct that taints the later '370 patent and renders it unenforceable. BSC's "taint" argument fails for two reasons:

First, the non-disclosure of Hillstead during the earlier '312 prosecution did not result from an intent to deceive the PTO. In responding to the charge of inequitable conduct, Dr. Fischell waived the attorney-client privilege and disclosed his privileged communications to BSC. Correspondence between Dr. Fischell and his long-time attorney, Morton Rosenberg, reveals the innocent reason why Hillstead was not cited during the '312 prosecution.

Second, any inequitable conduct during the '312 prosecution only could taint the separate '370 patent if there were an "immediate and necessary relation" between the alleged inequitable conduct and the issuance of the '370 patent. No such relation exists here. During '370 prosecution, Cordis cited Hillstead to the PTO, and did not make any use of the earlier non-disclosure of Hillstead. The Examiner reviewed Hillstead and decided to allow the '370 claims after reviewing that reference. In these circumstances, there is no "immediate and necessary relation" between the '370 patent and the alleged inequitable conduct during the prosecution of the separate '312 patent – and thus, no basis for holding that the '370 patent is unenforceable.

I Proposed Findings of Fact

A. The Prosecution of the Application for the '312 Patent

1. The application for the '312 patent, entitled "Stent Having a Multiplicity of Closed Circular Structures," was filed on February 24, 1994 by Robert Fischell ("Dr. Fischell") and his sons David Fischell, Ph.D. (who is a physicist) and Tim Fischell, M.D. (who is an interventional cardiologist).

2. Dr. Fischell is a prolific inventor. He is a named inventor on more than 120 U.S. patents. See Ex. A hereto. He was honored by the Intellectual Property Owners Association (the "IPO") as the Inventor of the Year for 1984, Ex. B hereto, and he has been honored on the floor of Congress for his contributions to medicine, space discovery and higher education. Ex. C (Congressional Record, Dec. 14, 2005, Extension of Remarks, E2531-32).¹

3. For the first two years after the application for the '312 patent was filed, Dr. Fischell prosecuted the application *pro se*. D.I. 255 at 77; PX 5003, Tab 9 at FWRAP 34. His sons were not involved in patent prosecution.

4. Starting in 1995, Morton Rosenberg represented Dr. Fischell in connection with foreign counterparts to the '312 application, but not in connection with the U.S. application for the '312 patent. D.I. 1055 at Tr. 955:12-17.² Mr. Rosenberg has practiced patent law for more than 30 years. He is a member of Rosenberg, Klein & Lee, the law firm he founded in 1972. Id. at Tr. 981:18-25. Mr. Rosenberg had known Dr. Fischell for many years and had represented him on patent matters since 1989. Id. at Tr. 954:23-25.

5. The European counterpart to the '312 application had the same title as the '312 application – "Stent Having a Multiplicity of Closed Circular Structures." It included three independent claims (claims 1, 13 and 15), and 17 dependent claims. DXB 11413. None of the independent claims mentioned undulating longitudinal structures.

¹ This Court may take judicial notice of Dr. Fischell's patents and of the honors he has received. See Selkridge v. United of Omaha Life Ins. Co., 360 F.3d 155, 162 n.5 (3d Cir. 2004); Oran v. Stafford, 226 F.3d 275, 289 (3d Cir. 2000); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 954 n.27 (Fed. Cir. 1993).

² D.I. 1054 contains the testimony of Robert Fischell from the hearing in February 2001. D.I. 1055 contains the testimony of Morton Rosenberg from that hearing. Both of these transcripts have been entered as part of the docket in C.A. No. 97-550-SLR.

6. In June 1995, Mr. Rosenberg received a Search Report from the European Patent Office for the European counterpart to the '312 application. DXB 10004. The Search Report from the European Patent Office listed one "X" reference (Sgro), four "Y" references (Wallsten [MedInvent], Inoue, Hillstead [Cordis] and Didcott) and one "A" reference (Cottenceau). Id. "X" references are "particularly relevant if taken alone"; "Y" references are "particularly relevant if combined with another document of the same category"; "A" references provide "technological background." Id.

7. When Mr. Rosenberg receives a search report, his practice for European prosecutions is to "carefully" review any "X" references, and "just scan Y references ... to see if anything jumps out at me as to a problem area that I may have in Europe." D.I. 1055 at Tr. 960:2-5. This is because in his experience, "you generally get rejected on the X references." Id. at Tr. 984:21-22. By contrast, "Y references ... are not particularly . . . relevant during the [European] prosecution." Id. at Tr. 984:22-24.

8. The first official action in the Fischells' European application (PX 5116) bears this out. In July 1996, the European Patent Office rejected claim 1 of the Fischells' European application based on Sgro. It did not mention any of the four "Y" references listed in the Search Report, and it did not reject any claims based on those references. PX 5116. There was nothing in this action that drew Mr. Rosenberg's attention to Hillstead. D.I. 1055 at Tr. 985:17-19.

9. In fact, the action by the European Patent Office made clear that *none* of the references in the search report, including Hillstead, were relevant to claim 8, which was the only claim in the European Application that required undulating longitudinals. PX 5116; D.I. 255 at 78. Claim 8 of the European application, like claim 8 in the U.S. application, was a

dependent claim which included an added requirement of "longitudinals ... of an undulating shape." That requirement was not part of the independent claims. As discussed above, undulating longitudinals serve to enhance flexibility for delivery to curved coronary arteries. The European Examiner stated that the "additional features of dependent claims 8 and 9 are not disclosed in their present form in *any* of the documents cited in the search report." PX 5116 at ¶ 7 (emphasis added).

10. During discovery in this case, Dr. Fischell waived the attorney-client privilege for all communications with his attorneys concerning the Hillstead reference. Those communications do not include *any* discussion of the Hillstead reference prior to the issuance of the '312 patent, either by Dr. Fischell or his attorney. There is nothing in the documentary record to indicate that Dr. Fischell was aware of Hillstead before the '312 patent issued.

11. Indeed, the attorney-client communications between Dr. Fischell and Mr. Rosenberg reveal an entirely innocent explanation for the non-disclosure of Hillstead during the '312 prosecution.

12. Mr. Rosenberg sent a copy of the European Search Report, and the references it cited, to Dr. Fischell, with a letter dated July 17, 1995. The letter stated:

Please note that the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application #566807 whose inventor is Jean-Claude Sgro.

We have made a Patentee Search to determine whether we have any corresponding patent [to Sgro] in the United States but have come up negatively. It may pay us to make a translation [of Sgro] from the French to determine if this is relevant.

DXB 11021 (emphasis added). Nothing in this letter calls attention to Hillstead. To the contrary, the letter describes the Sgro reference, which was the only "X" reference listed in the

Search Report, as the "only reference" that was particularly relevant. The letter did not mention the four "Y" references, including Hillstead.

13. As Mr. Rosenberg testified, this letter "reflect[ed] [his] state of mind in July 1995." D.I. 1055 at Tr. 986:16-18. He viewed Sgro as the only reference that was "particularly relevant" for European prosecution. Hillstead had not made "any impression" on him. Id. at 986:19-23. The Examiner of the European Application also found Hillstead to be of no relevance. PX 5116 at ¶7.

14. Taking his cue from his attorney's July 17, 1995 letter, Dr. Fischell focused on Sgro, which was the "only reference" that Mr. Rosenberg had identified in his letter as being "particularly relevant." DXB 11021; D.I. 1054 at Tr. 890:13-18, 913:10-914:6. He arranged to have Sgro translated from the French as Mr. Rosenberg had recommended, D.I. 1054 at Tr. 914:7-17, and he cited Sgro in the next IDS that was filed with the Patent Office. PX 5003, Tab 30, FWRAP 85.

15. Aside from the Sgro reference, Dr. Fischell had no recollection of reviewing the references listed in the Search Report. D.I. 1054 at Tr. 849:3-12, 888:5-12, 890:9-12, 915:2-16. Although Dr. Fischell could not rule out the possibility that he glanced at the other references, he had "no recollection of having seen [Hillstead]" prior to the issuance of the '312 patent in 1997. Id. at Tr. 852:1-6. Dr. Fischell focused on what Mr. Rosenberg said was important, and did not pay attention to the rest. Id. at Tr. 890:13-18, 913:10-914:6.

16. Dr. Fischell was unaware of the Y references, including Hillstead, listed in the Search Report until after the '312 patent issued in 1997, and he did not cite any of them during the '312 prosecution. Id. at Tr. 888:5-12, 890:9-12, 915:2-16.

17. After the issuance of the '312 patent, and after Cordis' acquisition of the patent rights, Dr. Fischell met with Cordis' attorneys from the firm of Patterson Belknap in the Spring of 1998. During this meeting, Dr. Fischell was shown a copy of the Hillstead patent. This meeting was the first time Dr. Fischell recalled seeing the Hillstead reference. Before this meeting, Dr. Fischell was "never cognizant of the Hillstead patent" Id. at Tr. 851:13-25; see also id. at Tr. 849:8-12, 850:17-20, 853:17-854:1, 888:5-12, 888:16-889:8, 915:22-916:8.

18. After Mr. Rosenberg sent the July 17, 1995 letter (DXB 11021) to Dr. Fischell, he put the European Search Report and the references it cited into his "EP" file for European prosecution. D.I. 1055 at Tr. 988:16-989:1. Mr. Rosenberg had no recollection of looking at Hillstead again until after the '312 patent issued. Id. at Tr. 986:24-987:4.

19. On November 15, 1995, the PTO notified Dr. Fischell that it could not locate the file for the application for the '312 patent. On November 29, 1995, Dr. Fischell submitted a reconstructed copy of the file to the PTO. PX 5003, Tab 21, FWRAP 68. On December 29, 1995, the PTO again notified Dr. Fischell that the file had been lost and that the PTO could not locate it after an "exhaustive search." PX 5003, Tab 22, FWRAP 69. The PTO sent Dr. Fischell a third such notice on February 5, 1996. PX 5003, Tab 23, FWRAP 70.

20. At that point, Dr. Fischell asked Mr. Rosenberg to take over U.S. prosecution. Mr. Rosenberg was substituted as attorney for the applicants on February 24, 1996. PX 5003, Tab 25, FWRAP 74-75; see also id. at Tab 24, FWRAP 71-73.

21. When he became involved in the U.S. prosecution, Mr. Rosenberg set up a separate file in his office for the U.S. prosecution. That file did not include any documents that were generated or received earlier, when he had been responsible only for foreign prosecution.

The European Search Report and the references it cited were only part of Mr. Rosenberg's European file. They were never part of his U.S. file. D.I. 1055 at Tr. 989:2-13.

22. When Mr. Rosenberg got involved, his first priority was reactivating the application. Through his efforts, the application regained "pending" status in May 1996. PX 5003, Tab 27, FWRAP 77.

23. On June 20, 1996, soon after the file regained active status, Mr. Rosenberg filed an IDS citing five references – Sgro, Wall, Sigwart, Palma and Lam – that Dr. Fischell brought to his attention. PX 5003, Tab 30, FWRAP 84-88; see also D.I. 1055 at Tr. 987:15-20; D.I. 1054 at 916:20-917:12. The IDS cited Sgro (which Mr. Rosenberg had singled out in his July 17, 1995 letter as being "particularly relevant"), but not any of the Y references, including Hillstead, listed in the European Search Report. D.I. 1055 at 990:2-7.

24. Mr. Rosenberg and Dr. Fischell did not have any reason to conceal Hillstead – just as they had no reason to conceal any of the other references from the Search Report.³ D.I. 1055 at Tr. 990:11-21.

25. In preparing the IDS, Mr. Rosenberg did not review the European Search Report or his EP file containing it. Id. at Tr. 989:18-20, 979:6-11. If he had reviewed his EP file and seen the European Search Report, he "would have just said, Bob, throw everything in, and we would have put it into the IDS." Id. at tr. 991:21-23; see also id. at Tr. 990:8-10.

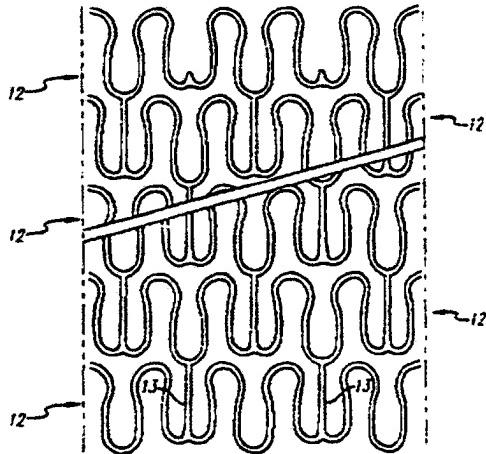
26. Rather than concealing references that he understood as disclosing stents with undulating longitudinals, Dr. Fischell affirmatively brought such a reference to the attention

³ As discussed infra at page 12, Dr. Fischell cited all of these references, including Hillstead, "as soon as" he became aware of them. D.I. 1054 at Tr. 922:12. They were cited only in continuations of the '312 patent, the '370 (PX 5001) and '604 (PX 5032) patents, because the '3112 patent had already issued. Both continuation patents have claims to undulating longitudinals and issued without any rejection over Hillstead. D.I. 1054 at Tr. 921:24-924:22; D.I. 1055 at 995:25-996:24.

of the PTO – and distinguished it on grounds that would have been equally applicable to Hillstead.

27. One of the references that Dr. Fischell and Mr. Rosenberg cited in the IDS was Lam's European Patent Application #662037. See PX 5003, Tab 30, FWRAP 85. Figure 5 from the Lam reference, PX 5044, is shown on the right. Mr. Rosenberg and Dr. Fischell cited Lam in the IDS because they "believed that the Lamb [sic] reference had undulating longitudinals." D.I. 1055 at Tr. 992:10-13. As Dr. Fischell testified:

FIG. 5



[T]he Lam reference was the first reference that I knew of that appeared to have undulating longitudinals and, therefore, since I became aware of it, I wanted us to file it with the Patent Office.

D.I. 1054 at Tr. 920:11-14.

28. As it turned out, Dr. Fischell and Mr. Rosenberg both misapprehended Lam's disclosure. Engineering drawings and stent patents that show stents in a planar view (*i.e.*, unfolded as a flat sheet, rather than in their cylindrical shape) usually depict them with their longitudinal axis running horizontally. However, Fig. 5 of Lam is oriented differently, with the longitudinal axis running vertically. Because of the unusual orientation of Fig. 5, what Dr. Fischell and Mr. Rosenberg perceived as longitudinal structures were in fact circumferential structures. D.I. 1055 at Tr. 992:10-24; D.I. 1054 at Tr. 927:8-18.

29. On the same day as the IDS, Dr. Fischell filed an Amendment in which he distinguished Lam by adding new application claim 28. That claim required that the undulating longitudinals' curved sections be joined to "straight sections" that run "generally parallel" to the stent's longitudinal axis – a feature that is shown in Fig. 8 of the Fischells' specification, but not taught in Lam as Dr. Fischell and Mr. Rosenberg (mis)understood it. PX 5003, Tab 29, FWRAP 80. Dr. Fischell and Mr. Rosenberg "wrote this [claim language] to overcome the undulating longitudinal structure that we saw in ... Figure 5 of Lam." D.I. 1054 at Tr. 921:7-9; see also D.I. 1055 at Tr. 992:25-994:8; D.I. 1054 at Tr. 920:6-22. Consistent with his understanding at the time, Dr. Fischell told the PTO that Lam "provides for (an) undulating structure(s)" (PX 5003, Tab 30, FWRAP 86), and distinguished it as "not provid[ing] for any undulating structures being coupled to any [straight] longitudinal structures, as is necessary to the subject Patent Application system." Id.; see also D.I. 1055 at Tr. 993:6-994:8.

30. If Dr. Fischell had been aware of Hillstead, he could have distinguished it on the same grounds.

31. A Notice of Allowability issued on December 1996. PX 5003, Tab 37, FWRAP 108. The '312 patent then issued on July 1, 1997. PX 5000.

B. The Prosecution of the Application for the '370 Patent

32. The application that issued as the '370 patent was filed on May 28, 1997 as a continuation from the application that issued as the '312 patent.

33. In early 1998, Cordis acquired the '312 patent and the application for the '370 patent. In April 1998, Cordis' outside counsel at Patterson Belknap met with Dr. Fischell. During this meeting, counsel for Cordis showed Dr. Fischell the Hillstead reference. D.I. 1054 at

Tr. 851:13-25, 889:6-8. Until then, he was "completely unaware of it." Id. at Tr. 887:17-19; see also id. at Tr. 849:8-12, 850:17-20, 853:17-854:1, 888:5-12, 888:16-889:8, 915:22-916:8.

34. At about the same time, Mr. Rosenberg learned from Cordis' counsel that Cordis was about to sue BSC for infringement of the Fischell patents, or already had done so. D.I. 1055 at Tr. 994:9-16. Mr. Rosenberg then searched his files, including his EP file, and brought everything he found to the attention of Cordis' counsel – including the references listed in the European Search Report. Id. at Tr. 995:14-18. Until then, Mr. Rosenberg had not been aware of Hillstead after becoming involved in U.S. prosecution. Id. at Tr. 994:9-12.

35. In May 1988, Dr. Fischell filed an IDS that cited 41 U.S. patents, seven foreign patent documents and thirteen articles. The cited references included the four "Y" references and one "A" reference from the European Search Report, *i.e.*, Wallsten, Inoue, Hillstead, Didcott and Cottenceau. PX 5002, Tab 16, FWRAP 191-93.

36. On June 1, 1998, Dr. Fischell filed another IDS, citing seven additional references. Id. at Tab 23, FWRAP 274-276.

37. On August 1, 1998, the Examiner initialed each of the references on PTO Form 1449A – indicating that he had considered each of them. Id. at Tab 18, FWRAP 196-200; Tab 25, FWRAP 278.

38. The Examiner did not comment on Hillstead and did not reject any claims based on it. D.I. 1055 at 996:3-7.

39. During prosecution of the '370 patent, Dr. Fischell did not make any use of the non-disclosure of Hillstead during the '312 prosecution. During the '370 prosecution, he never stated or suggested that undulating longitudinal structures did not exist in the prior art.

40. In examining the application for the '370 patent, the Examiner had the opportunity to – and did – examine the '370 claims on their own merits in light of Hillstead. PX 5002, Tab 18, FWRAP 196-200. He concluded that the '370 claims are patentable over the art of record, including Hillstead. The '370 patent issued on March 9, 1999, with Hillstead among the "References Cited." PX 5001.

II Proposed Conclusions of Law

A. There Was No Inequitable Conduct During the '370 Prosecution

1. BSC has not alleged, and could not allege, that there were any acts of inequitable conduct during the prosecution of the application for the '370 patent. As the Federal Circuit noted on appeal in this case, "there was no separate inequitable conduct found during the prosecution of the '370 patent." Cordis v. BSC, 2006 WL 1876839 at *4.

2. Accordingly, the '370 patent could only be held unenforceable if there were an "immediate and necessary relation" between the '370 patent and the alleged inequitable conduct in the '312 patent. Id. at *4. As discussed below, there is no such relation – Dr. Fischell did not make any use of the earlier non-disclosure of Hillstead during the prosecution of the '370 patent. To the contrary, Hillstead was affirmatively disclosed during the '370 prosecution, and the Examiner reviewed the Hillstead reference before issuing the '370 claims. Without an "immediate and necessary relation" there is no possibility of taint.

B. There was No Intent to Conceal During the '312 Prosecution

3. In addition, BSC cannot show "taint" because Dr. Fischell did not intentionally conceal the Hillstead reference during the earlier '312 prosecution. Without clear

and convincing evidence of an earlier intent to conceal Hillstead from the PTO, there can be no possibility of "taint."

4. An applicant cannot make "a deliberate decision to withhold a known material reference," Baxter Int'l., Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998), if the applicant was unaware of the reference in the first place. A reference that is not known cannot be intentionally concealed. The applicant's "*actual* knowledge of the reference's existence must be proved." Nordberg, Inc. v. Telsmith, Inc., 82 F.3d 394, 397 (Fed. Cir. 1996) (emphasis in original); see also American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984). "[T]here is no duty to disclose art of which an applicant is unaware." Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005).

5. As Dr. Fischell testified, he had no recollection of seeing Hillstead at any time before his meeting with Cordis' counsel in the Spring of 1998 – after the '312 patent issued. As this Court found, Dr. Fischell and Mr. Rosenberg testified "that they did not look at the Hillstead patent until April 1998" D.I. 255 at 83 (citing D.I. 1054 at Tr. 849-50, 882-89, 914-916; D.I. 1055 at Tr. 955, 978-80, 995). The Court did not question the truthfulness of this testimony in 2002 and it should not do so today – years after the fact.

6. In order to prove that Dr. Fischell wrongfully withheld Hillstead from the Patent Office, BSC must show – clearly and convincingly – that he was aware of Hillstead and intentionally chose to conceal it. Dr. Fischell's uncontradicted testimony shows the opposite – that he was unaware of Hillstead until Cordis' counsel showed it to him in 1998, after the '370 patent issued. "Conjecture alone is not sufficient to show an intent to deceive to support the

defense of inequitable conduct." In re Hayes Microcomputer Products, Inc. Patent Litig., 982 F.2d 1527, 1546 (Fed. Cir. 1992).

C. Documentary Evidence Reveals the Innocent Explanation for the Non-Disclosure of Hillstead During the '312 Prosecution

7. The documentary record reveals the innocent explanation for why Hillstead was not cited during the '312 file history. As discussed above, Dr. Fischell received the European Search Report with a letter from his attorney, advising that the "*the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application #566807 whose inventor is Jean-Claude Sgro.*" DXB 11021 (emphasis added). After being told by counsel that Sgro was "the only ... particularly relevant" reference, id., it is not surprising that Dr. Fischell focused on Sgro and not on the other references listed in the Search Report. He cited Sgro in the next IDS, but was "never cognizant of the Hillstead patent until April of '98," D.I. 1054 at Tr. 851:18-19, after the issuance of '312 patent.

8. These facts, confirmed by documentary evidence, provide the innocent explanation for why Hillstead was not cited during the '312 prosecution. They make this case very different from situations where there is "no ... good faith explanation of why [a reference] was never cited". Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997). See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1182 (Fed. Cir. 1995) ("Things can 'fall through the floorboards' and not arise from an intent to deceive."). As the Federal Circuit has recognized, "[a] patentee's [innocent] oversights are easily magnified out of proportion by one accused of infringement" Northern Telecom. Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990) (citation omitted).

9. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1395-96 (Fed. Cir. 1988), is more closely on point. There, the Federal Circuit reversed a finding of inequitable conduct and held that there was "not clear and convincing evidence to support the district court's finding of a deliberate intent to conceal" where a letter from foreign counsel called attention to various references without calling attention to the un-cited reference. This case presents similar facts, which explain why Dr. Fischell cited Sgro in an IDS, but paid no attention to Hillstead.

10. It also is understandable why Mr. Rosenberg did not pay attention to Hillstead when he received the European Search Report in June 1995. At the time, Mr. Rosenberg had no role in U.S. prosecution and did not have any disclosure obligations as a matter of law. Molins, 48 F.3d at 1178 n.6; see also 37 CFR §1.56. He did not consider Hillstead significant for European prosecution, and he did not remember it when he later assumed responsibility for U.S. prosecution in 1996. D.I. 1055 at Tr. 983:19-987:4.

D. Dr. Fischell Had No Duty to Conduct a Prior Art Search

11. This Court acknowledged Dr. Fischell's and Mr. Rosenberg's testimony that "they did not look at the Hillstead patent until April 1998," D.I. 255 at 83, and did not question the truthfulness of that testimony. Instead, it faulted Dr. Fischell and Mr. Rosenberg for not "[taking] responsibility for conducting a prior art search directed to the added limitation of 'undulating' longitudinals" Id.

12. This criticism is wrong on the law. It is well-settled that "an applicant ... has no duty to conduct a prior art search . . ." American Hoist, 725 F.2d at 1362; see also Bruno, 394 F.3d at 1351 n.4 ("there is no general duty to conduct a prior art search"); Nordberg, 82 F.3d at 397 (same).

E. Dr. Fischell Did Not Cultivate Ignorance of Hillstead

13. Since there is no duty to conduct a prior art search, the Federal Circuit asked this Court to address whether it "faulted Dr. Fischell merely for failing to conduct a prior art search, or whether [it] faulted Dr. Fischell for 'cultivat[ing] ignorance' with respect to the Hillstead reference." Cordis v. BSC, 2006 WL 1876839 at *4 (quoting FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)).

14. Of course, "an applicant who knew of the art or information cannot intentionally avoid learning of its materiality through gross negligence, *i.e.*, it may be found that the applicant 'should have known' of that materiality." FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987). An applicant also cannot "cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art." FMC, 836 F.2d at 526 n.6.

15. But at the same time, "it is impossible to disclose the unknown" and charges of inequitable conduct based on non-disclosure accordingly "may be rebutted by a showing that ... [the] applicant did not know of that art or information". FMC, 835 F.2d at 1415; see also Bruno, 394 F.3d at 1351n.4 ("there is no duty to disclose art of which an applicant is unaware").

16. In this case, Dr. Fischell was unaware of Hillstead until after the '312 patent issued. As Dr. Fischell testified, he was not cognizant of Hillstead until Cordis' counsel at Patterson Belknap showed him that reference at a meeting in the Spring of 1998. D.I. 1054 at Tr. 851:13-25, 915:22-916:8. As this Court found, Dr. Fischell and Mr. Rosenberg testified "that they did not look at the Hillstead patent until April 1998 . . ." D.I. 255 at 83. No evidence contradicts this testimony.

17. As the Federal Circuit explained, if Dr. Fischell "knew of the Hillstead patent" and "knowing that the Hillstead patent contained information that was likely material" to the patentability of the '312 patent "purposefully avoided obtaining knowledge of the details of that patent," that could serve as a basis for an intent to deceive. Cordis v. BSC, 2006 WL 1876839 at *4. However, the record does not permit such findings. There is no evidence that Dr. Fischell was aware of Hillstead prior to April 1988. Thus, there is no evidence Dr. Fischell thought about Hillstead during the prosecution of the '312 patent, much less that he viewed it as likely material to patentability. Certainly, there is no evidence that Dr. Fischell "purposefully avoided" learning the details of the Hillstead patent.

18. This Court faulted Dr. Fischell and Mr. Rosenberg for not "conducting a prior art search directed to the added limitation of 'undulating' longitudinals" (D.I. 255 at 83) and thus, "'putting their heads in the sand' regarding prior art" (D.I. 255 at 89) but nothing more. This Court did not suggest that Dr. Fischell knew of the Hillstead patent and purposefully cultivating ignorance of its details. Nor would the evidence support any such finding.

19. As this Court found, Dr. Fischell and Mr. Rosenberg were not aware of Hillstead at any relevant time to the prosecution of the '312 patent. They did not cultivate ignorance of its contents.

F. The Citation of Lam is Further Evidence of Good Faith

20. The citation of Lam in the belief that it has undulating longitudinals demonstrates that Dr. Fischell and Mr. Rosenberg had no intent to conceal references with that feature.

21. "When examining intent to deceive, a court must weigh all the evidence, including evidence of good faith." Akron Polymer Container Corp. v. Exxel Container, Inc., 148

F.3d 1380, 1384 (Fed. Cir. 1998); see also Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1580 (Fed. Cir. 1997).

22. Rather than concealing references with undulating longitudinals, Dr. Fischell cited Lam in the belief that it "had undulating longitudinals." D.I. 1054 at Tr. 918:11-16; see also D.I. 1055 at Tr. 992:10-13. When he cited Lam, he advised the PTO that it provides for undulating structures, PX 5003, Tab 30, FWRAP 86, and he then distinguished its undulating structures from those with "straight sections" that are "generally parallel to the longitudinal axis of the stent" and are "joined continuously" to "undulating sections," as shown in Fig. 8 of the '312 patent and as required by new application claim 28, which Dr. Fischell submitted on the same day as the IDS citing Lam. PX 5003, Tab 29, FWRAP 80. (Of course, Hillstead could have been distinguished on the same basis – if Dr. Fischell had been aware of it.).

23. This evidence of good faith confirms that the non-disclosure of Hillstead resulted from lack of awareness, not a deliberate attempt to conceal stents with undulating longitudinal structures.

G. There is No "Immediate and Necessary Relation" Between the '370 Patent and the Non-Disclosure Of Hillstead During The '312 Prosecution

24. The prosecution of the '370 patent was entirely innocent and "no separate inequitable conduct [was alleged or] found during the prosecution of the '370 patent." Cordis v. BSC, 2006 WL 1876839 at *4. BSC accordingly is relegated to arguing that the non-disclosure of Hillstead during the '312 prosecution "taints" the separate '370 patent, even though Dr. Fischell disclosed Hillstead during the '370 prosecution and the Examiner considered that reference before allowing the '370 claims.

25. In the absence of any inequitable conduct during the '370 prosecution, the '370 patent could be held unenforceable only if there is an "immediate and necessary relation" between the '370 patent and the alleged inequitable conduct in the '312 patent. Id. at *4-5. The requisite "immediate and necessary relation" is entirely absent here. In prosecuting the '370 patent, Dr. Fischell did not make any use of – or obtain any benefit from – the non-disclosure of Hillstead during prosecution of the '312 patent. During the '370 prosecution, Dr. Fischell did not state or suggest that undulating longitudinal structures did not exist in the prior art. To the contrary, he affirmatively disclosed Hillstead during the '370 patent prosecution. With Hillstead having been cited in an IDS, the Examiner had the opportunity to review that reference, and to consider the '370 claims on their merits in light of it. In these circumstances, there is no "immediate and necessary relation" between the issuance of '370 patent and the non-disclosure of Hillstead during the '312 prosecution.

26. The circumstances required for an "immediate and necessary relation" are entirely different from those present here. For example, in Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933), the plaintiff had entered into a "corrupt transaction" to "suppress" evidence in a prior litigation against the Byers Machine Company. Id. at 243-44. After prevailing in the Byers case in reliance on that "corrupt transaction," the plaintiff then used the decree of validity it obtained in the Byers case to its advantage in moving for a preliminary injunction in the case at bar. Id. at 246. The Supreme Court held that "[t]he use actually made of th[e] decree [in the Byers case] is sufficient to show that plaintiff did not come with clean hands in respect of any cause of action in these cases." Id. at 247. The fact that the plaintiff acted with unclean hands with respect to all of the asserted patents was essential to the Supreme Court's

holding that an "immediate and necessary relation" existed between the "unconscionable act" in the Byers case and the case at bar. *Id.* at 245.

27. Consistent with Keystone Driller, the Federal Circuit has held that related patents are unenforceable in cases unlike this one – where inequitable conduct "permeated the[ir] prosecution," Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 812 (Fed. Cir. 1990), in ways that had an "'immediate and necessary relation,'" *id.* at 810, quoting Keystone Driller, 290 U.S. at 245, to the patent-in-suit. In Consolidated Aluminum, the plaintiff fraudulently concealed its best mode CS1-B slurry from the specification of its '917 patent, and then used that wrongful conduct to its advantage in subsequent patent applications to present the CS1-B slurry "as part of the invention disclosure ... and as a basis for its successful arguments in prosecuting the applications that became the other patents-in-suit." *Id.* at 811. The Federal Circuit found that the "concealment of the CS1-B slurry from the '917 patent permeated the prosecution of the other patents-in-suit and renders them unenforceable." *Id.* at 812.

28. Here, in contrast, the non-disclosure of Hillstead was confined to the '312 patent. There is no evidence that the nondisclosure in the '312 patent "affected" or "carried over to the '370 prosecution." Cordis v. BSC, 2006 WL 1876839 at *5. There is nothing about the "applicant's characterization of the prior art" during '370 prosecution that makes use of the prior nondisclosure. *Id.* Hillstead was affirmatively disclosed and considered during the prosecution of the '370 patent. Applicants made no use whatsoever of the non-disclosure of Hillstead in the '312 patent during the prosecution of the '370 patent.

29. Unlike Consolidated Aluminum, the prosecution history of the '370 patent refutes rather than "establish[es]" an "'immediate and necessary relation'" between the alleged inequitable conduct during the '312 prosecution and the equity sought – the enforcement of the

'370 patent. *Id.*, 910 F.2d at 810. There is no "immediate and necessary relation" between the issuance of the '370 patent over Hillstead and the earlier non-disclosure of Hillstead during prosecution of the separate '370 patent. BSC's "taint" theory accordingly fails.

H. The Submission of Hillstead Among Sixty Other References Does Not Diminish Its Disclosure

30. BSC has tried to discount the disclosure of Hillstead by suggesting that the PTO may have been diverted from its mandatory duties – consideration of cited references – because Hillstead was disclosed among sixty other references. This argument runs counter to settled law. "It is presumed that public officials do their assigned jobs." Northern Telecom, 908 F.2d at 939 (citing American Hoist, 725 F.2d at 1359).

31. Although Hillstead was submitted along with sixty other references, the Examiner reviewed each reference, including Hillstead. The Examiner memorialized his review of Hillstead by initialing PTO Form 1449A, thereby "indicating his consideration of [that reference]". Molins, 48 F.3d at 1184.

32. Moreover, the submission of multiple references at the same time and without discussion is not evidence of an intent to conceal those references from the PTO. In Molins, the Federal Circuit rejected as clearly erroneous a finding that "burying" an important reference without discussion among 94 references cited in an 11-page IDS showed an intent to conceal (id. at 1184):

Hirsch and Smith discovered a multitude of uncited references in related foreign files after the '563 patent issued. They disclosed the references within a relatively short time The examiner initialed each reference, indicating his consideration of the same *These circumstances therefore do not present clear and convincing evidence of intent on the part of [the applicants] to conceal Wagenseil from the PTO during the reexamination. Thus, the court's finding in this regard is clearly erroneous*, and the

determination that the method of disclosure constituted inequitable conduct cannot be sustained.

(emphasis added). This reasoning is equally applicable here.

33. Cordis paid \$52 million for the patent rights it is asserting in this case.

After acquiring those rights, it wanted to make sure that all arguably relevant references were submitted to the PTO, and it did that with commendable alacrity. It did nothing wrong.⁴ After acquiring the application for the '370 patent, Cordis brought Hillstead to Dr. Fischell's attention, D.I. 1054 at Tr. 851:13-25, 889:6-8, 915:22-916:8, and promptly cited it in an IDS. PX 5002, Tab 16, FWRAP 191-93; D.I. 1054 at Tr. 921:24-922:12. The Examiner then considered the cited references, including Hillstead, before allowing the '370 claims. PX 5002, Tab 18, FWRAP 196-200. As in Molins, under these circumstances, the disclosure of Hillstead among other references is not evidence of an intent to conceal it from the PTO.

34. Cordis did not have an obligation to address Hillstead or otherwise call attention to that reference during the '370 prosecution. The MPEP, in effect as of May 1998 and as of today, only requires applicants to discuss the contents of references that are "not in the English language." MPEP § 609(A)(3) (6th ed. July 3, 1997) (emphasis in original). "[T]he earlier PTO requirement that the applicant explain the relevance of the references listed [in an IDS] was removed in 1992." Fiskars v. Hunt Mfg. Co., 221 F.3d 1318, 1327 (Fed. Cir. 2000); see also Molins, 48 F.3d at 1184 (finding no obligation to "particularly point out to the examiner

⁴ In citing 61 references in the May 1998 IDS, Cordis was motivated by the realities of patent litigation. By May 1998, Cordis had decided to bring suit on the '370 patent once it issued. It understood that inequitable conduct is often raised as a defense in infringement cases, see Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) (describing the frequent invocation of this defense as a "plague"), and it wanted to be safe rather than sorry, by avoiding an accusation that any arguably relevant art was withheld.

the relevance of cited material prior art" even where numerous references are cited). Under the MPEP and the Federal Circuit's case law, there was no obligation to describe the Hillstead reference or otherwise call attention to it when it was cited during the '370 prosecution.

35. Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556 (Fed. Cir. 1983), does not require a different conclusion. That case addressed a "narrow issue": whether "an applicant, knowing that misrepresentations have been made to the examiner of his application," can take steps to "alleviate [the] effect [of the misrepresentation]." Id., 722 F.2d at 1571-72. Neither Rohm & Haas nor any other Federal Circuit decision suggests that non-disclosure of a reference during prosecution of one patent gives rise to any obligation to call attention to that reference in connection to a related but separate patent in which the reference was disclosed and no misrepresentations occurred. The disclosure of Hillstead during the '370 prosecution in itself precludes taint from the earlier non-disclosure.

36. As discussed above, the submission of Hillstead without comment among other references is not evidence of an intent to conceal it from the PTO. Hillstead was affirmatively disclosed during the '370 prosecution and the '370 claims were examined on their own merits in light of that reference. The PTO is presumed to do its job. Moreover, the fact that the Examiner initialed Hillstead in PTO Form 1449A shows that he reviewed that reference before allowing the '370 claims. Molins, 48 F.3d at 1184. In the absence of any "immediate and necessary relation" between the '370 patent and the earlier non-disclosure, the non-disclosure of Hillstead during the '312 prosecution does not taint the separate '370 patent.

CONCLUSION

For the reasons set forth above, Cordis respectfully requests the Court to find that BSC failed to prove by clear and convincing evidence that the '370 patent is unenforceable due to inequitable conduct.

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CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of November, 2006 the attached **CORDIS'** **PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW ON INEQUITABLE CONDUCT** was served upon the below-named counsel of record at the address and in the manner indicated:

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